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EXAMINER

SWIGER III, JAMES L

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al. (US Patent 6,485,518) in view of Davison (US Patent 6,530,926).

Cornwall et al. teaches an intervertebral support and fusion system that allows for transfacet fixation using fasteners (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See Cols. 1 and 2 and also see Col. 3, lines 40-52). It is noted that the method of Cornwall et al. prefers a minimally invasive method (Col. 2, lines 18-21) and teaches that a single-cannula approach is possible in the spirit of a minimally-invasive, percutaneous procedure. It is further noted that Cornwall et al. also teaches the step of positioning at a preferred angle, considered inclining, at a preferred angle in performing a percutaneous and posteriolateral procedure. Cornwall et al. also teach the delivering of a first fastener to the surgical location, and also advancing the screw from a first vertebra and into a second vertebra.

Cornwall et al. teaches the claimed device except for the specific use of inserting into a patient an access device wherein said access device has a different diameter at a

Art Unit: 3775

distal end and has two configurations and also the step of inserting multiple fasteners.

Modification of Cornwall et al to use the device of Davison allows improved access in performing the spinal surgery, yielding more space in the surgical area.

Davison teaches a percutaneous access device and cannula that is inserted into a patient (Fig. 5, 10, and Col. 2, lines 58-63), and wherein the access device has a first and second configuration (Col. 3, lines 3-39) and, with regards to claims 8-13 and 23, multiple fasteners can be inserted through the cannula to secure vertebrae. Davison teaches that multiple fasteners may be inserted (see Col. 13, lines 15-25, and Abstract). Additionally, in use of the device, the screws 30a and 30b are slightly angled to perform transfacet fixation.

Additionally, a substantially perpendicular plane with respect to the spine, denoted by the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws. It is noted that the term "crossing" is not interpreted as the same thing as inclining. The plane represented in the drawing is a visual landmark and as noted previously, the cannula is inclined to insert a bone fastener with respect to this point. Thus, Davis teaches the step, of the device moving from a plane generally perpendicular to the spine of the patient at an established angle. It is an "angled approach." The cannula may be slightly (ie. substantially perpendicular) angled to complete the procedure and deliver the screws accordingly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the method of Cornwall et al.

Art Unit: 3775

having/using the access device as taught by Davison to have improved access to the spinal area with a first and second configuration at an end for adjoining and securing vertebrae and also for inserting multiple screws in the vertebral area.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Cornwall et al. '518 and Davison '926 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener or securing device is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of the combination of Cornwall et al. '518 and Davison '926 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926. The combination of Cornwall et al. '518 and Davison '926 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the

Art Unit: 3775

art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posteriorly through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 11/4/2008 have been fully considered but they are not considered persuasive.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is

Art Unit: 3775

(571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733